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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

ZITOMER, STEPHANIE W

ART UNIT

PAPER NUMBER

1634

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#32

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

08/836,734

Applicant(s)

BECKMANN ET AL.

Examiner

Stephanie Zitomer

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 9-14 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 15-18 and 20-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 28.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### **Application status**

1. Receipt of Applicant's election of SEQ ID NO:4 with traverse in paper no. 13 filed May 22, 2002 is acknowledged.

### **Response to Applicant's traversal of paper no. 30 restriction**

2. Applicant confirms the previous election of Group I (claims 1-4, 8 and 20) in paper no. 10 filed April 29, 1998. (See Examiner's response to traversal in paper no. 30 mailed April 24, 2002.) Applicant notes that "claims 21 and 22 do not appear to have been included in any of Groups I-III" and requests that this be done. In response, it is pointed out that claims 21 and 22 were first presented in paper no. 13 filed April 5, 1999, more than a year after the mailing of the restriction, in paper no. 7, on February 37, 1998. As the present Office action is the first in this application, claims 21 and 22 are addressed herein. As to the traversal of the sequence restriction, Applicant's argument that SEQ ID NOS:1-5, 68 and 69 all are parts of the same gene is well taken. Examiner had noted the same and nucleotide sequences SEQ ID NOS:1-5, 68 and 69 have been searched.

### **Claims rejoined**

3. In view of the finding that SEQ ID NOS: 1-5, 68 and 69 are free of the prior art, the product claims 1-4, 8 and 20 will be allowable pending 112, second paragraph, corrections. Therefore, applicant is entitled under PCT Rule 13 to a first claim group comprising claims drawn to the product, a process of making the product and a process of using the product. Claims are selected in order of their presentation. As there is no claim to a process of making the product, the first group comprises product claims 1-4, 8, 20 and process of using (including kit) claims 15-18. Dependent claim 16 is drawn to multiple methods each defined by a patentably distinct primer sequence and claim 18 is drawn to multiple kits each defined by "selected primers". Therefore, to include claims 16 and 18 in the allowable claim group, applicant must elect a single primer pair to which claims 16 and 18 will be restricted and the claim must be amended to be drawn only to that pair of nucleotide sequences. The elected primer pair must be the same for claims 16 and 18.

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**Lack of unity of claims 21 and 22**

4. Claims 21 and 22 lack unity of invention with claims 1-4, 8, 20, 15 and 16 because, under PCT Rule 13, they are drawn to further processes of using the product and Rule 13 permits only one process of using to be grouped with the product. Therefore, claims 21 and 22 are withdrawn from prosecution.

**Claims withdrawn from prosecution: Summary**

5. Claims 9-14 and 19 have not been considered because they are non-statutory under 35 U.S.C. 101 as stated in paper no. 7. Claims 5-7 and 20c) are drawn to amino acid sequences which are structurally and functionally distinct chemical compounds from the nucleic acid sequences of claims 1-4, 8 and 20a) and b) and therefore do not share a common technical feature (nucleic acids) with the latter claims. Under PCT Rule 13, the amino acid sequence claims thus constitute a second product group. Therefore, claims 5-7 and 20c) like claims 21 and 22 have been withdrawn from prosecution. Claims 1-4, 8, 15-18 and 20 are presently under prosecution.

**Missing abstract**

6. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

**References listed in specification**

7. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been listed on form 1449 or cited by the examiner on form PTO-892, they have not been considered.

**Reference requested**

8. Applicant is requested to provide to the examiner a copy of the reference cited as "(John Libbey, Eurotext, 1993)" at page 5, lines 7-8. The specification states (page 5, lines 8-9) that this reference "bear[s] one of the DNA sequence (*sic*) of the invention". Therefore, it appears that the reference may be relevant prior art to at least one of the claimed sequences and the citation is insufficient to permit the Patent Office to obtain it.

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### **Informalities**

9. The disclosure is objected to because of the following informalities:

(a) The sequences in Table 2 (page 11) lack SEQ ID NOS:. If these sequences are not in the Sequence Listing both the hard copy and the CRF of the Sequence Listing must be redone as amendment is not permitted (37 CFR 1.821).

(b) In the description of Figure 2 (amendment filed August 30, 2001), "Figure 2" should be "Figures 2A-2C" and the SEQ ID NO: should be provided for the sequence of 2B as it is for the 2A and 2C sequences.

(c) Citations in the specification require completion: page 5, lines 17-18 "Accession number pending"; page 5, line 30, "Richard in preparation"; page 16, line 32, "Allamand, submitted"

Appropriate correction is required.

### **Claim 22 objected to: Multiple dependency**

10. Claim 22 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim may depend from multiple claims in the alternative only. See MPEP § 608.01(n).

### **Rejection under 35 U.S.C. 101: Product of nature**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claims 1-4, 8 and 20 are rejected under 35 U.S.C. 101 because the claimed "nucleic acid sequence comprising..." reads on a naturally occurring genomic sequence which is not a category of invention. It is suggested that this rejection may be overcome by inserting "isolated" before "nucleic acid sequence" in the claims.

### **Rejections under 35 U.S.C. 112, second paragraph: Indefiniteness**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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12. Claims 1-4, 8, 20 and 15-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 1-4 are highly confusing in the designation of claim parts by numbers which may be readily confused with claim numbers. It is suggested to change the numbers to lower case letters as in amended claim 18.

(b) Claims 1-4 are confusing because "able to code for a protein..." in part 3) is *non sequitur* to SEQ ID NOS: 68 and 69 which are defined in the specification as "flanking genomic regions" (page 6, description of Figure 2) which would not be expected to encode the protein. It is suggested to delete part 3) because it is redundant over part 2) in that "a part of" SEQ ID NO:5 which is the cDNA cannot "code for a protein...". (The entire cDNA encodes the protein.)

(c) Claims 1-4, 15 and 16 are confusing because "derived from" in claim 1, part 4) and in claims 15 and 16, part d) is an indeterminate phrase which is not defined in the claims or in the specification. It is suggested to replace the phrase with "obtained from".

(d) Claim 3 is confusing because it is unclear whether the claim intends a vector or a cell in a patient having LGMD2 disease. Note that the latter is a product of nature and subject to rejection and 101. It is suggested to direct the claim to a vector comprising the nucleic acid sequence of claim 1 under the control of a promoter which directs expression of the calpain protein as described in the specification at page 4, lines 26-28.

(e) Claim 8 is confusing and lacks antecedent basis in claim 1 because it recites transformation or transfection with a nucleic acid sequence comprising "part of the nucleic acid sequence according to claim 1" whereas part 3) of claim 1 already is "part of" the nucleic acid sequence. Thus it is unclear whether the "part of" in claim 8 is "part of" the sequence "part" in claim 1 part 3). It is suggested to delete part 3) of claim 1 as previously suggested and to delete "all or part of" from claim 8.

(f) Claim 15 is confusing due to the presence of a superfluous "of" in the first line.

(g) Claim 20 is confusing because it contains subject matter withdrawn from prosecution in c). It is suggested to delete part c) and insert --and-- at the end of part a).

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**Conclusion**

**13. Claims 1-4, 8, 15-18 and 20 are free of the prior art but rejected on other grounds.**

**14.** Applicant is reminded that claims nonelected with traverse must be canceled before the application can be allowed.

**15.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-3985. The examiner can normally be reached on Monday through Friday from 9:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The official fax phone number for this Group is (703) 308-4242. The unofficial fax number is (703) 308-8724. The examiner's Rightfax number is 703-746-3148.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196. For questions and requests relating to formal matters contact Patent Analyst Tiffany Tabb at 703-605-1238.



Stephanie Zitomer, Ph.D.

June 25, 2002